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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,067	07/10/2003	David G. Beer	UM-08196	8445
72960	7590	10/16/2007		
Casimir Jones, S.C. 440 Science Drive Suite 203 Madison, WI 53711			EXAMINER SANG, HONG	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 10/16/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/617,067

Applicant(s)

BEER ET AL.

Examiner

Hong Sang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) 3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RE: Beer et al.

1. Applicant's response filed on 8/15/07 is acknowledged.
2. Claims 1-3 are pending. Claims 4-14 are cancelled. Claim 3 is withdrawn from further consideration as being drawn to non-elected inventions. Claim 1 is amended.
3. Claims 1 and 2 are under examination.

Objections Withdrawn

4. The objection to claims 1, and 4-7 because the claims contain non-elected inventions is withdrawn in view of applicants' amendment to the claims.

Rejections Withdrawn

5. The rejection of claims 1, 2 and 4-7 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for detecting lung cancer in a subject, comprising detecting the presence of GSTM4 polypeptide in lung tissue of said subject, does not reasonably provide enablement for a method for identifying a stage of lung cancer in a subject, a method for providing a prognosis of lung cancer in a subject comprising detecting the presence of GSTM polypeptide in lung tissue of said subject is withdrawn in view of applicant's amendment to the claims.

6. The rejection of claims 1, 2 and 4-7 are rejected under 35 U.S.C. 102(a) as being anticipated by Chen et al. (Clin. Cancer Res., 2002, July 1st, 8: 2298-2305) is withdrawn in view of applicant's submission of 37 C.F.R. 1.132 declaration.

Objections Maintained

7. The objection to the disclosure because it contains an embedded hyperlink and/or other form of browser-executable code is maintained due to applicant's failure to address the issue.

8. The objection to the disclosure because of the following informality of the Brief Description of the Drawings is maintained due to applicant's failure to address the issues.

9. The objection to the specification because no Tables 3, 4 and 5 are found in the specification is maintained due to applicant's failure to respond to the objection.

Response to Arguments

Claim Rejections - 35 USC § 102

10. The rejection of claims 1 and 2 under 35 U.S.C. 102(b) as being anticipated by Cantlay et al. (Thorax, 1994, 49:1010-1014) is maintained.

The response states that Cantlay does not teach the claim step of diagnosing cancer by detecting the increased levels of GSTM4 relative to the levels in non-

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cancerous tissue. Cantlay does not teach detection of GSTM4, but rather detects expression of GSTM1. Cantlay specifically states that no attempt was made to quantitate the levels of GSTM1 protein.

Applicant's arguments have been carefully considered but are not persuasive. Cantlay et al. teach immunohistochemical detection of GSTM1 polypeptide in lung tissues obtained from 21 human subjects having lung cancer using polyclonal antibody for GSTM1, wherein two cases of the 21 showed strong staining, seven were weakly stained and the remainder were negative (see page 1011, 1st paragraph, and page 1013, 2nd paragraph). Cantlay et al. specifically states that GSTM4 has greater than 90% sequence homology with GSTM1, the polyclonal antibody could react with the product of both genes (see page 1011, 2nd paragraph). Therefore, by detecting GSTM1 using the polyclonal antibody, Cantlay also detected GSTM4 in lung tissue. Because Cantlay used immunohistochemical detection, Cantlay would have detected GSTM4 expression in both lung cancerous cells and normal adjacent cells. The intensity of the staining for some cells is at least 4 fold stronger than that for non-stained cells (see Figures 2(d) and (e)). Therefore, Cantlay teaches all the active steps of the claims.

11. The rejection of claim 1 rejected under 35 U.S.C. 102(b) as being anticipated by Rowe et al. (Biochem. J. 1997, 325, 481-486) is maintained.

The response states that Rowe does not teach the claim step of diagnosing cancer by detecting increased levels of GSTM4 relative to the levels in non-cancerous tissues.

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Applicants' arguments have been carefully considered but are not persuasive. Rowe et al. teach detection of GSTM4 polypeptide in lung tissues obtained from different subjects using antibody (see page 482, right column, 4th paragraph, Figure 1B and Table 1). Rowe et al. teach comparing the level of GSTM4 polypeptide between different subjects (see Table 1). Rowe et al. do not disclose that the subjects are lung cancer patients, therefore, Rowe et al. teach detecting the GSTM4 polypeptide in lung tissue, and further comparing the GSTM4 level to a non-cancerous lung tissue control. Therefore, Rowe et al. teach all the active steps of claim 1.

For this rejection, the preamble and the wherein clause is not given patentable weight.

The determination of whether each of these clauses is a limitation in a claim depends on the specific facts of the case. In *Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329, 74 USPQ2d 1481, 1483 (Fed. Cir. 2005), the court held that when a "whereby" clause states a condition that is material to patentability, it cannot be ignored in order to change the substance of the invention." *Id.* However, the court noted (quoting *Minton v. Nat'l Ass'n of Securities Dealers, Inc.*, 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed.Cir. 2003)) that a "whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited." *Id.* (see MPEP 2111.04[R-3]).

MPEP 7.37.10 states "A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for

completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951)".

12. The rejection of claims 1 and 2 under 35 U.S.C. 102(a) as being anticipated by Chen et al. (Mol. Cell. Proteomics, 2002, April, 1:304-313) is maintained.

The response states that Chen does not teach the claim step of diagnosing cancer by detecting increased levels of GSTM4 relative to the levels in non-cancerous tissues.

Applicant's arguments have been carefully considered but are not persuasive. Chen et al. teach detection of GSTM4 polypeptide in lung cancerous tissues and comparing the level of the GSTM4 polypeptide detected in cancerous tissue to that detected in normal lung tissues (see page 306, Table, and page 304, last paragraph). Chen et al. teach identifying the lung tumor stage (see page 310, and Table III). As indicated in the previous office action, Chen et al. do not specifically teach detecting the expression level of the TSTM4 polypeptide in lung cancer that is 4 fold higher than that in normal lung tissue. Because Chen et al. detected the same protein in the same type of lung cancer tissues, their detecting would encompass detecting the expression level of GSTM4 polypeptide that is 4 hold higher than that in normal lung tissue.

Conclusion

13. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hong Sang, Ph.D.
Art Unit 1643
September 24, 2007

/Christopher Yaen/
Primary Examiner
Art Unit 1643
October 10, 2007